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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,665	06/12/2001	Douglas R. Daum	279.358US1	4223
21186	7590	12/01/2003	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 12/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,665

Applicant(s)

DAUM, DOUGLAS R.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/20/03 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The Applicant's has amended claims 1, 3-17 and 19-30 to overcome the prior art of record, hence a new grounds of rejection is established for claims 1, 3-17 and 19-30 in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

2. Claims 31, 33 and 35 stand rejected under 35 U.S.C. 102(b) as being anticipated by Sheldon et al. (US 6044297).

Sheldon et al. disclose an implantable medical device and teach detecting a condition, patient position/ activity, correlative to hypotension. The pacing rate is adjusted based on the metabolic need as measured by an array of accelerometers (col. 1 @ 6-16; col. 7 @ 23-36; col. 9 @ 10-13; col. 22 @ 4-9).

Claim Rejections - 35 USC § 103

3. Claims 32 and 34 stand are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US 6044297) in view of Combs et al. (US 5957861). Sheldon et al. teach hypotension can be associated with fluid shifts and suggest an indirect measurement of fluid level changes, sleep cycle and position change, to monitor the need for an adjusted pacing rate. Combs et al. teaches a more direct and exact means to measurement of fluid changes using respiratory rate and/or impedance. As discussed in paragraph 2 of this action, Sheldon et al. discloses the claimed invention except for:

- using a means for detecting thoracic impedance to detect hypotension (claim 32),
- and
- detecting a breathing signal (claim 34) associated with activity.

Combs et al. disclose a device (10) with an impedance monitor for discerning edema through the evaluation of impedance, and teach the following elements combinable, for the reasons noted, to modify the implantable medical device as taught by Sheldon et al.:

As to detecting thoracic impedance, a thoracic impedance signal is detected using a thoracic signal detection module (17) (figure 1; col. 3 @ 16-25; col. 4 @ 33-34), detecting impedance associated with a fluid shift away from the thorax. Transthoracic impedance measurements give a good indication of the level of edema (abnormal accumulation of fluid) in patients (col. 1 @ 11-16). Edema provides a sign of failing heart circulation (col. 1 @ 28-30), and is manifest in pulmonary edema of increased water in the lungs (col. 2 @ 38-42). Edema is indicative of patient health and the need for modified therapy (col. 2 @ 12-16 and 30-36; col. 3 @ 13-15; col. 4 @ 1-4; col. 5 @ 56-61; col. 9 @ 48-59; col. 12 @ 40-50; col. 13 @ 1-5; col. 13 @ 52-58; col. 15 @ 24-27). Therapy is provided based at least in part of the baseline portion of the detected thoracic impedance (col. 4 @ 1-4; col. 7 @ 13-33; col. 11 @ 48-53). Impedance is monitored to indicate health status and the need for therapy modification in order to automatically provide treatment responsive to the onset of edema (col. 4 @ 1-4).

As to detecting a breathing signal, breathing is detected and therapy provided based exclusively or in part on the detected breathing (col. 5 @ 36-45; col. 12 @ 1-16;

col. 13 @ 20-26; col. 13 @ 59-64) to provide multiple data points to confirm the diagnosis so appropriate treatment can be automatically provided at the onset of edema (col. 4 @ 1-4).

The Applicant's arguments relative to claims 31-35, filed 10/20/03, have been fully considered, but they are not convincing. The Applicant asserts claims 31-35 are written in means-plus function form, the disclosure teaches the use of transthoracic impedance in the hypotension detection circuit, and Sheldon et al. does not teach transthoracic impedance to detect hypotension, hence the "means for detecting a hypotension in a subject" is not disclosed by Sheldon et al.. The Examiner disagrees. The Applicant discloses a transthoracic impedance signal (page 8, starting at line 8) or an accelerator signal (page 9, starting at line 17) can be used to detect hypotension in the hypotension detection circuit. Sheldon et al. teaches an accelerometer signal to detect hypotension, hence Sheldon et al. disclose the instant invention (col. 1 @ 6-16; col. 7 @ 23-36; col. 9 @ 10-13; col. 22 @ 4-9).

4. Claims 1, 3-8, 10, 13, 17, 19-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferek-Petric et al. (US 5913879) in view of Standberg (EP 0 620 420 A1) and further in view of Combs et al. (US 5957861).

Ferek-Petric et al. teaches an implantable therapy device that detects venous pooling (correlative to hypotension), read as detecting fluid shift away from the thorax, using a flow detector and provides therapy in response to the fluid shift (abstract; figure 2; col. 1 @ 7-11;

col. 3 @ 17-63). Ferek-Petric et al. notes the blood flow measurement can be made by impedance measurements (col. 2 @ 51-55) as taught by Strandberg using electrodes (col. 5 @ 11 – col. 6 @ 4).

As discussed in the previous paragraph of this action, modified Ferek-Petric et al. disclose the claimed invention except for:

- a sensor correlative to the subject's metabolic need (claims 1 and 17), the signal being a breathing signal (claims 8 and 24) or an accelerometer (claim 25),
- the fluid shift from the thorax being detected by a signal component (claim 3), the component being increase in the baseline (claim 4),
- attenuating a high frequency component of the thoracic impedance (claim 7), and filtering (claim 20) with the impedance frequency value being 0.01 to 0.5 Hz (claims 5 and 21), or approximately 0.1 Hz (claims 6 and 22).

Combs et al. disclose a device (10) with an impedance monitor for discerning edema through the evaluation of impedance, and teach the following elements combinable, for the reasons noted, to modify the modified implantable therapy device as taught by modified Ferek-Petric et al.:

As to a sensor correlative to the subject's metabolic need (claims 8 and 24), Combs et al. teach the use of sensor subsystems, one being an activity sensor in the form of a respiratory/breathing signal (claims 8 and 24) or accelerometer (claim 25) to provide multiple data points that correlate activity and changes in the level of edema so diagnosis is confirmed and appropriate pacing therapy provided (col. 4 @ 1-4; col. 5 @ 36-45; col. 12 @ 1-16;

col. 13 @ 20-26 and 59-64; col. 14 @ 45-53).

As to the fluid shift from the thorax being detected by an increase in the baseline (claims 3 and 4), a thoracic impedance signal is detected using a thoracic signal detection module (17) (figure 1; col. 3 @ 16-25; col. 4 @ 33-34), detecting impedance associated with a fluid shifts in the thorax. Transthoracic impedance measurements give a good indication of the level of edema (abnormal accumulation of fluid) in patients (col. 1 @ 11-16). Edema provides a sign of failing heart circulation (col. 1 @ 28-30), and is manifest in pulmonary edema of increased water in the lungs (col. 2 @ 38-42). Changes in edema are indicative of patient health and the need for modified therapy (col. 2 @ 12-16 and 30-36; col. 3 @ 13-15; col. 4 @ 1-4; col. 5 @ 56-61; col. 9 @ 48-59; col. 12 @ 40-50; col. 13 @ 1-5; col. 13 @ 52- 58; col. 15 @ 24-27). Therapy is provided based at least in part of the baseline portion of the detected thoracic impedance (col. 4 @ 1-4; col. 7 @ 13-33; col. 11 @ 48-53). Impedance is monitored to indicate health status and the need for therapy modification in order to automatically provide treatment responsive to changes in edema (col. 4 @ 1-4).

As to attenuating a high frequency component of the thoracic impedance (claim 7), a high frequency component of the thoracic impedance signal is attenuated (col. 6 @ 58 – col. 7 @ 33) to reduce unwanted data/ noise from the signal so an accurate diagnosis and appropriate treatment can be automatically provided at the onset of edema (col. 4 @ 1-4).

As to filtering (claim 20) and the impedance frequency value being 0.01 to 0.5 Hz (claims 5 and 21), or approximately 0.1 Hz (claims 6 and 22), the filter, read as the averager/ low pass filter, uses the 0.05Hz to 0.5 Hz frequency range to establish optimize signal quality enabling automatic treatment at the onset of edema (col. 4 @ 1-4; col. 7 @ 6-15).

5. Claims 9, 11, 12, 14-16, 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferek-Petric et al. (US 5913879) in view of Standberg (EP 0 620 420 A1) and further in view of Combs et al. (US 5957861) and further in view of Sheldon et al. (US 6044297). As discussed in paragraphs 3 and 4 of this action, modified Ferek-Petric et al. disclose the claimed invention except for:

- detecting and comparing the instantaneous and long-term components of the activity signal to thresholds to correlate the condition to hypotension (claims 9 and 26), and
- detecting hypotension correlated and not correlated with posture (claim 11 and 12),
- increasing the rate responsive factor by steps (claims 14 and 28), increasing and decreasing the rate responsive factor (claims 15 and 29) and returning the rate responsive factor over a third period of time (claims 16 and 30).

Sheldon et al. disclose an implantable medical device and teach detecting a condition, patient position/ activity, correlative to hypotension. The pacing rate is adjusted based on the metabolic need as measured by an array of accelerometers (col. 1 @ 6-16; col. 7 @ 23-36; col. 9 @ 10-13; col. 22 @ 4-9). Sheldon et al. teach the following elements combinable, for the reasons noted, to modify the modified implantable therapy device as taught by modified Ferek-Petric et al.:

As to the activity signals (claims 9 and 26), activity levels associated with two timers are used to reflect activity, the activity being correlated with blood pressure to determined pacing therapy so the therapy is appropriately updated (col. 11 @ 20 – col. 12 @ 9).

As to hypotension and posture, monitoring the blood pressure and position enables correlation both to a hypertension associated with a change in posture and to a hypertension not associated with a change in posture so the therapy can be customized to the subject's specific needs (col. 7 @ 23-36; col. 9 @ 10-13).

As to the rate responsive factor (claims 14-16 and 27-30), the rate responsive factor is stepped (col. 7 @ 31-34; col. 11 @ 63 – col. 12 @ 9). US 5354317 to Alt, incorporated by reference (col. 2 @ 51-53; col. 3 @ 7-17), discloses variable rate pacing to provide electrical output signals uniquely responsive to pre-selected positions, including gradual rate changes (Alt - abstract) to provide optimal pacing therapy for the subject's specific needs.

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
11-17-03

Angela D. Sykes

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